

REMARKS

The instant invention is drawn *inter alia* to methods of treating arthritis using androstenediones.

Claim 1 has been amended to more fully identify the claimed invention. Support for this amendment can be found in dependent claims 4-6 and 8-10, for example. The amendment to the claim is fully-supported by the application as filed and adds no new matter.

Claim Rejections - 35 U.S.C. § 112

Claims 1-11, 22-29 and 31-32 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly not being enabled. The Examiner states that the "instant specification fails to provide information to one skilled in the art to practice the method of preventing arthritis without undue experimentation" (emphasis in original, page 2, last full sentence). Applicant respectfully traverses this rejection as it applies to the claims as amended.

The Patent Office carries the initial burden of establishing a reasonable basis to question enablement. In re Wright, 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993). A disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in claiming the invention must be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements relied upon for enablement.

The Patent Office must establish a reasonable basis for rejecting a claim as nonenabled under 37 U.S.C. § 112. This includes providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement. In re Marzocchi, 439 F.2d 220, 223-24, 169 U.S.P.Q. 367, 369-70 (C.C.P.A. 1971). An assertion by the Patent Office that the enabling disclosure is NOT commensurate in scope with the protection sought must be supported by evidence or reasoning substantiating the doubt expressed by the Office. In re

Dinh-Nguyen et al., 492 F.2d 856, 181 U.S.P.Q. 46 (C.C.P.A. 1974).

The type of information considered sufficient to establish a reasonable basis for rejecting a claim as nonenabled under 37 U.S.C. § 112 is exemplified in In re Wright, 999 F.2d 1557, 27 U.S.P.Q.2d 1510 (Fed. Cir. 1993). The applicant in that case sought claims directed to ALL recombinant vaccines for RNA viruses which functioned by recognizing envelope proteins on the virus. The Examiner rejected the claims as nonenabled based upon a combination of (i) the inability of others to develop a successful vaccine for many RNA viruses (including AIDS) and (ii) an article which indicated that RNA viruses are an extremely diverse group of viruses with substantially divergent protein envelopes. The Court of Appeals for the Federal Circuit upheld the rejection as supported by adequate evidence only after a comprehensive discussion in which the court emphasized the necessity of providing objective evidence (e.g., the article indicating the extreme diversity of protein envelopes on RNA viruses). Hence, the Court of Appeals for the Federal Circuit has made it abundantly clear that rejection of a claim as nonenabled must be supported by more than a statement that the disclosure is generic.

Applicant submits that the Examiner has NOT met this initial burden. The application claims the administration of a known compound to identifiable patients using known methods for administering the composition. Therefore, Applicant respectfully requests that the enablement rejection under 35 U.S.C. § 112, first paragraph be withdrawn and that the claims be allowed.

Claim Rejections - 35 U.S.C. § 103

Claims 1-3, 7, 11, 22, 31 and 32 stand rejected under 35 U.S.C. § 103(a) for alleged obviousness over Lardy (U.S. Patent 5,585,371) in view of Merck Manual, 16th ed. (1992) pages 1342-1343. Applicant respectfully traverses this rejection as it applies to the claims as amended.

The Examiner states "Lardy teaches that 7-oxo-DHEA can enhance the immunological activity and treat infection caused by virus, bacteria, fungus, veriod and prion ... Merck Manual teaches infectious arthritis is resulting from infection of the synovial tissues with infectious agents and bacteria being the most often etiological agents ... It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ 7-oxo-DHEA in a method of treating infectious arthritis" (page 5).

Claim 1 has been amended to identify three forms of arthritis: rheumatoid arthritis, osteoarthritis, and fibromyalgia, rendering this rejection moot. In view of the above, Applicant respectfully requests that the obviousness rejection under 35 U.S.C. § 103(a) be withdrawn and that the claims be allowed.

SUMMARY

Applicants assert that the claimed invention is in condition for allowance and notification to that effect is respectfully requested. In order to facilitate rapid allowance, the Examiner is invited to contact the undersigned at the telephone number below.

Any fees due in relation to the timely filing of this Response are hereby authorized to be deducted from Deposit Account No. 501536.

Respectfully submitted,

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